**UNITED STATES DISTRICT COURT**
**DISTRICT OF MASSACHUSETTS**

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| IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION | ) | MDL NO. 1456<br>Civil Action No. 01-12257-PBS |

**DEFENDANTS' MEMORANDUM IN SUPPORT OF ENTRY OF PROPOSED CASE MANAGEMENT ORDER NO. 10**

At the March 8, 2004 status conference ("March 8 Conference"), the Court requested revised proposed Case Management Orders ("CMOs") from the parties, based on a phased discovery approach that would allow the Court to decide the important issues in this litigation during the summer of 2005. Plaintiffs were directed to choose five companies (the "Track 1 Defendants") to include on a "fast track" schedule for discovery and motions practice that would enable the Court to reach this objective. Claims against the remaining AMCC defendants and the Together Rx claims were to proceed on separate tracks, so that the Court's decisions with respect to the Track 1 Defendants could provide guidance for the remainder of the litigation.

Plaintiffs' proposed CMO will not allow the Court to meet these objectives. Instead of selecting five companies for the "fast track," Plaintiffs have selected five defendant groups totaling fourteen different operating companies and 136 of the 321 drugs identified in the AMCC. Moreover, plaintiffs' proposal allows for unlimited and unstructured discovery of these fourteen companies and 136 drugs on an accelerated schedule pursuant to a series of specific discovery rules that reach well beyond the

requirements of the Federal Rules of Civil Procedure. In short, plaintiffs' proposal allows for draconian and unnecessary burdens to be placed on the Track 1 Defendants that would make it virtually impossible for discovery and briefing to be completed in the time frame requested by the Court. Furthermore, plaintiffs' proposal provides little structure to the progress of the remaining parts of the litigation.

Defendants' proposal, which establishes three tracks for the next stages of this litigation, provides a more reasoned approach. As discussed in more detail below, Track 1 provides for structured discovery, pursuant to guidelines to be established by agreement if possible, of five separate operating companies (the "Track 1 Defendants") on a timetable that will allow the Court to reach class certification at the earliest practicable stage and summary judgment in the summer of 2005. Track 2 similarly provides for structured discovery of the remaining AMCC defendants, on a timetable staggered behind Track 1, so that the Court's rulings on discovery, class certification and summary judgment with respect to Track 1 can provide guidance for the remainder of the litigation. Track 3 provides for discovery of Together Rx and its member companies focused on the threshold antitrust issues, pursuant to a schedule that trails the Track 1 timetable by a mere 90 days.

Unlike plaintiffs' proposal, this framework allows the Court to make substantial progress on the important issues in this massive litigation, without unnecessary burden and expense. Accordingly, defendants respectfully submit that the Court should adopt defendants' proposed CMO 10.

## DISCUSSION OF THE PROPOSED CMOs

### I. TRACK 1 – The "Fast Track"

Instead of choosing five companies for the "fast track," plaintiffs selected five defendant groups: the AstraZeneca Group, the GSK Group, the BMS Group (Bristol-Myers Squibb Co., Oncology Therapeutics Network Corp. and Apothecon Inc.), the Johnson & Johnson Group (Johnson & Johnson, Centocor, Inc., Janssen Pharmaceutica Products, L.P., McNeil-PPC, Ortho-Biotech Products, L.P.), and the Schering-Plough Group (Schering-Plough Corporation and Warrick Pharmaceuticals Corporation). As noted above, these five defendant groups include fourteen separate operating companies and account for 136 of 321 drugs listed on Appendix B to the AMCC -- more than 40% of the total number of drugs at issue in this case.

Moreover, plaintiffs' proposal allows for unlimited discovery of these 14 companies and 136 drugs – a truly massive undertaking that would be impossible to achieve on the Court's proposed timeframe. In fact, the four Track 1 companies that were engaged in discovery prior to the hearing on November 21, 2003 have reviewed close to 10 million pages of documents relating to only 10 drugs, at a total cost of over $5 million, and many of those productions are still ongoing. See, e.g., Supplemental Memorandum of Johnson & Johnson et al.; Supplemental Memorandum of Bristol-Myers Squibb Co. As the Court recognized in the Together Rx context, unlimited product-specific discovery into 136 drugs would not only take years and tens of millions of dollars to accomplish, it "would just sink the litigation." See Tr. 24. Moreover, such unlimited product-specific discovery is simply unnecessary to reach the important issues on class certification and summary judgment.

In contrast, as demonstrated below, defendants' proposal provides for structured discovery of five separate operating companies on a timetable that reaches class certification at the earliest practicable time and allows the Court to decide summary judgment motions during the summer of 2005.

**A. Selection of the Five Track 1 Companies**

Defendants propose that the number of Track 1 Defendants be limited to five companies, as directed by the Court at the March 8 Conference, Tr. at 42, and not five company groups. As demonstrated in the separate submissions of Bristol-Myers Squibb, Johnson & Johnson and Schering and Warrick, the companies listed by plaintiffs as part of each of these defendant groups are in fact separate operating companies with different management, different practices and policies, and different product lines. Defendants' proposed CMO 10 would require plaintiffs to select one operating company from these defendant groups so that the Track 1 Defendants would consist of five separate operating companies and a more manageable number of drugs through which the Court could test plaintiffs' theories on class certification and the merits.

**B. Scope of Track 1 Discovery**

Unlimited product-specific discovery would not only make it virtually impossible to complete discovery and briefing on the timetable requested by the Court, it is simply unnecessary to the adjudication of class certification and summary judgment. Accordingly, defendants' proposed CMO 10 provides for the establishment of reasonable discovery guidelines either by agreement of the parties or with the assistance of a Magistrate Judge or Special Master.

The establishment of guidelines for Track 1 discovery will focus the parties on the important factual and legal issues involved in the adjudication of class certification and

summary judgment with respect to plaintiffs' claims. The Court's February 24 Order provides significant guidance in this respect. There, the Court observed that plaintiffs allege "three primary paradigms" of fraudulent conduct. Slip op. at 4. The Court described the first paradigm as the alleged manipulation of the spread between the actual cost of drugs and the AWP that is used to set the level of reimbursement for physician-administered drugs under Part B of the Medicare program. Id. The Court described the second paradigm as the alleged manipulation of AWPs and other fraudulent practices aimed at encouraging pharmacy benefit managers ("PBMs") to place manufacturers' products -- mostly self-administered pills -- on the PBMs' formularies. Id. The third paradigm described by the Court, discussed below in Section III of this memorandum, is the alleged antitrust conspiracy in connection with Together Rx. Id.[1]

Track 1 discovery with respect to many of the Medicare Part B drugs involved in the first paradigm is well underway pursuant to the Court's prior orders. Additional documents relating to such drugs and documents relating to other Part B drugs identified for the Track 1 Defendants in the AMCC can likely be produced within the timeframe contemplated by the Court.[2] Defendants are not proposing any other specific guidelines for this discovery apart from those previously or to be negotiated, ordered, or contained in the Federal Rules of Civil Procedure.

Guidelines must, however, be placed on discovery relating to the second paradigm – the PBM fraud claims. Just as the Court has recognized with respect to the

[1] Defendants deny that any of these paradigms – even if the underlying facts were true – would state a claim for relief.

[2] It is important to note that discovery from third parties has been delayed thus far, in large part due to plaintiffs' motion for a protective order which effectively resulted in a stay of discovery from certain third party health plans. The Court denied that motion at the March 8 conference and the parties will be in a position to proceed with that discovery once an order is issued.

Together Rx claims, unlimited drug-by-drug discovery is not necessary to resolve the liability issues under the PBM paradigm. For example, discovery of the PBM claims could, and indeed should, be limited to determining the threshold issue of whether there are in fact any fraudulent relations between the manufacturers and the PBMs, and the PBMs and their customers, before requiring massive, drug-by-drug discovery of all products that are marketed through PBMs.

Such a guideline would be consistent with the allegations of the AMCC. Plaintiffs allege that defendants and PBMs engaged in "hidden profit-making schemes" in which PBMs garnered rebates and other "soft dollars" that the PBMs failed to disclose to their customers, pocketed "secret spreads" between actual drug costs and the prices charged to health plans and their members, and kept "secret discounts" provided by defendants in association with the PBMs' mail-order operations. See AMCC ¶ 654. Each of these alleged practices involves the relationship between defendants and PBMs and PBMs and third-party payors. Thus, discovery into the manufacturer-PBM-customer relationship is all that is needed to test these allegations.

In fact, in the February 24 Order, the Court identified the scope of discovery that would test these allegations:

- "marketing materials about the AWP's for brand-name drugs sent from manufacturers to PBM's";
- "written representations of the AWP's sent by the manufacturers";
- "'written and oral communications discussing, negotiating and confirming the placement of a Defendant drug manufacturer's drug on a particular PBM's formulary'";
- "written communications, including checks, relating to rebates, kickbacks and other financial inducements"; and

- regular meetings between "salespersons from manufacturers [and] PBM's to promote their products and the fraudulent AWP scheme."[3]

Guidelines which provided for discovery of these types of communications, as well as the relevant PBM contracts and documents related to the PBMs' relationships with their customers, would avoid the unnecessary cost and burden of drug-by-drug discovery, without sacrificing the discovery necessary to test both the merits of plaintiffs' claims and whether such claims can be litigated on a class basis.[4]

This is just one powerful example of the guidelines that can, and should, be established for Track 1 Discovery to allow the parties and the Court to make substantial progress with this massive litigation.

**C. Track 1 Schedule**

The only significant difference between the parties' Track 1 schedules is that in defendants' proposal there is a moderate acceleration in the deadlines for both class certification and summary judgment briefing. Such an accelerated schedule is necessary so that class certification can be addressed "at the earliest practicable time," Fed. R. Civ. P. 23(c)(1), prior to the adjudication of summary judgment. The summary judgment briefing deadlines have also been moved forward to accommodate the Court's desire to reach these issues by summer 2005. See Tr. at 46.

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[3] Drug-specific discovery should be confined to the topics discussed above that relate directly to the defendant-PBM relationship with regard to each drug. For example, if a defendant wrote a letter to a PBM explaining why a designated drug should be included in that PBM's formulary, that letter would be produced, but if a similar letter was addressed to a physician extolling the virtues of that same drug, that letter would not be produced.

[4] Indeed, defendants believe that such discovery will demonstrate that there is no "typical" relationship, contract, rebate program or discount arrangement that is negotiated between manufacturers and PBMs or between PBMs and plaintiff funds or other third party payors. Similarly, the limited discovery taken to date reveals that, rather than being "secret" as alleged by plaintiffs, slip op. at 11-12, the rebates sent to PBMs by the manufacturers were well known to and shared with third-party payor plaintiffs.

## II. TRACK 2 – THE REMAINING AMCC DEFENDANTS

Plaintiffs' proposed CMO provides little structure to the Track 2 process. In contrast, defendants' proposed CMO provides for the establishment of guidelines on the timing and scope of Track 2 discovery, so that Track 2 proceeds on a slower pace than Track 1. This staggered approach will allow the parties to take into account any guidance and direction from the Track 1 process.

## III. TRACK 3 – TOGETHER RX

Defendants propose a separate Track 3 schedule for the Together Rx claims that is 90 days behind the Track 1 schedule, with the exception of an accelerated deadline for fact discovery. Defendants believe that defendants' approach is preferable to plaintiffs' proposal, which provides the same schedule for both Track 1 and Together Rx, because the Together Rx claims are separate claims involving different issues and in some cases different defendants. Defendants' proposal is also more consistent with the Court's intent to treat the Together Rx claims independently of the other claims. See Tr. at 8, 22, 31.

Defendants' Track 3 proposal also better reflects the Court's intentions with regard to limitations on the scope of discovery with regard to Together Rx. See id. Defendants propose that discovery relating to Together Rx claims be limited to discovery related to (1) plaintiffs' allegations of horizontal conspiracy, and (2) general Together Rx practices and policies, including each of the Together Rx Defendants' practices and policies relating to their participation in Together Rx. As contemplated by the Court, Tr. 8, 9, 31, there should be no product-specific discovery relating to the Together Rx drugs, unless and until the Together Rx Defendants inform the Court that they intend to argue in opposition to the certification of any Together Rx class(es) that product-specific differences would prevent the certification of any Together Rx class(es). The Court

recognized that discovery on 170 drugs in the Together Rx context was "too many drugs" and "would just sink the litigation." Tr. 24.

Plaintiffs concede that -- as the Court observed at the March 8 Conference -- the claims asserted against Together Rx Defendants neither require nor support drug-specific discovery. See Plaintiffs' Mem. at 2. Having admitted that, plaintiffs then outline in general terms a broad and potentially time-consuming and expensive discovery plan that could be construed as doing precisely that. The Together Rx Defendants do not believe that it would be efficient or practical to litigate the scope of anticipated discovery in the abstract and, therefore, will not here attempt to respond to plaintiffs' general description of the types of information they intend to seek. Because it will be easier for the Court to resolve specific discovery disputes in context, the Together Rx Defendants reserve the right to object to specific discovery requests with respect to the Together Rx claims when they are made.

## IV. ADDITIONAL DISCOVERY RULES AND OTHER MATTERS

Plaintiffs propose 11 additional discovery rules and a separate proposal regarding notification of settlement discussions. Defendants' responses to each of these proposals are set out below in essentially the same order as plaintiffs' proposals.

1. Government Investigations: There are three significant differences between plaintiffs' and defendants' proposals on this issue. First, defendants propose that the CMO require production of documents previously produced to governmental bodies only if the documents relate to drugs named for a given defendant in Appendix A to the AMCC. Plaintiffs' proposal, which suggests that documents related to any drug must be produced, should be rejected as yet another attempt to expand the scope of this case. Second, given the volume of documents involved, defendants' 45-day

deadline for Track 1 Defendants is more reasonable than the 30-day time limit proposed by plaintiffs. See Plaintiffs' Proposed CMO, at II.2. Similarly, an extended deadline is appropriate for Track 2 Defendants. Finally, defendants' proposal contains a provision providing that any individual defendant may seek relief by motion from the CMO's provisions regarding prior government productions. Now that active discovery has begun, blanket disclosure of prior government productions may not be appropriate in some circumstances.

2. NDCs: Plaintiffs should not be permitted to expand their list of drugs further by including all NDCs (National Drug Codes) for a drug where those NDCs are not referenced in Appendix A to the AMCC.[5] See Plaintiffs' Proposed CMO, at II.2. The Court has repeatedly stressed that the drugs at issue in the case are only those drugs identified in Appendix A to the AMCC. Expanding the list of drugs even further to include NDCs not mentioned in the AMCC would make it that much more difficult to complete discovery within the timeframe contemplated by the Court.

3. Redactions: Contrary to plaintiffs' proposal (at II.3), there should be no restrictions on the redaction of irrelevant information from confidential documents. Such redactions can be an appropriate means of protecting information of a particularly sensitive nature when that information is not relevant to the action or not likely to lead to the discovery of admissible evidence. Indeed, plaintiffs have made such redactions in their own document productions.

[5] The FDA assigns each drug product a unique NDC which indicates a specific strength, dosage form, formulation and package size for that product. Indeed, in opposition to defendants' motion to dismiss the AMCC, plaintiffs relied on the fact that they had listed in Appendix A each drug at issue by NDC as evidence of the alleged particularity of the AMCC. They should not now be allowed to expand this case beyond that universe.

4. Confidentiality Stamps: There is no need to restrict the manner in which a document is stamped "confidential." See Plaintiffs' Proposed CMO, at II.4. Requiring the re-production of documents bearing such stamps would be costly and unduly burdensome.[6] If relevant information on a document is illegible because of such a stamp, the parties can meet and confer regarding how best to correct the situation.

5. Electronic Format: Defendants propose that unless otherwise agreed by the parties, documents maintained in the usual course of business in an electronic form may be produced in an electronic format. Defendants should not, as proposed by plaintiffs (at II.5), have to bear the expense and burden of converting documents into a "usable electronic format" that is compatible with plaintiffs' computer systems and/or software. The precise manner of producing electronic documents can best be resolved through negotiations between the parties. Indeed, there is substantial federal court authority for the proposition that the requesting party must bear a significant portion of the costs associated with this type of restoration and conversion.[7]

6. Embellishments on the Federal Rules: Defendants have complied with and will continue to comply with this Court's prior discovery orders and the Federal Rules of Civil Procedure. There is no need to impose the additional requirements proposed by plaintiffs (at II.6, II.9-10) regarding the production of documents, filing of

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[6] The documents stamped "confidential" that plaintiffs attach to their memorandum were produced to the government in that format. Prior to production to plaintiffs, plaintiffs inspected these documents, saw how they were stamped, and nevertheless requested that the documents be copied without alteration. Requiring the producing defendant to pay for a second production of the same documents would be unfair and unwarranted under the circumstances.

[7] See Murphy Oil USA, Inc. v. Flour Daniel, Inc., No. Civ. A. 99-3564, 2002 WL 246439, at *3-6 (E.D. La. Feb 19, 2002); see also Medtronic Sofamor Danek, Inc. v. Michelson, M.D., No. 01-2373-M1V, 2003 WL 21468573, at *3-8 (W.D. Tenn. May 13, 2003) (holding that requesting party must bear 40 percent of restoration, searching and de-duplicating costs where parties stood to "equally benefit" from the electronic discovery); Zubulake v. UBS Warburg LLC, 216 F.R.D. 280, 289 (S.D.N.Y. 2003) (ordering requesting party to bear 25 percent of restoration costs in connection with "narrowly tailored" document request).

written responses to document requests, or noticing and production of witnesses beyond those imposed by the Federal Rules. Such restrictions would serve only to constrain the flexibility of the parties to negotiate reasonable arrangements that take into account business realities, witness schedules, and the volume of information requested. In light of the tight timeframes proposed for Track 1, both parties will have every incentive to negotiate in good faith to resolve disputes and complete discovery in a timely fashion.

7. Rolling Productions: The Track 1 Defendants shall make a good faith effort to begin a rolling production no later than thirty (30) days following the meet and confer described in paragraph III.3 of defendants' proposed CMO, and to complete production of all documents within one hundred twenty (120) days of the meet and confer. This should address the parties' concerns regarding the need to proceed with document productions as expeditiously as possible without imposing undue burdens on either party. See Plaintiffs' Proposed CMO, at II.7.

8. Privilege Logs: Defendants propose that privilege logs shall be provided 14 days after completion of a production, and shall cover each document withheld from production, as well as each redaction from a document produced. There is no basis in the Federal Rules of Civil Procedure for requiring that a log be accompanied by an affidavit supporting each claim of privilege, as proposed by plaintiffs (at II.8). Furthermore, no defendant shall be required to create a privilege log with respect to its CMO 5 production that was not produced to a government agency in the first instance.

9. Copying: There is no basis for prohibiting a party from reducing or enlarging the size of a document as part of the photocopying process, provided that the legibility of the copy is not materially altered. See Plaintiffs' Proposed CMO, at II.11.

Indeed, adjusting the size of a document can make it easier to read and/or insure that all marginalia are visible and not cut off as part of the copying process.

10. Other Actions: Plaintiffs have no basis for their proposal that defendants be required to notify them of any attempts to settle any of the claims before this Court or in any other jurisdiction. See Plaintiffs' Proposed CMO, at V. Defense counsel have the right and the responsibility to litigate these matters in their clients' best interests without disclosing such intentions or settlement strategies.

**V. MISCELLANEOUS**

Defendants propose an April 9, 2004 deadline for answering the AMCC filed on January 22, 2004. Defendants also propose to clarify that CMO 10 does not authorize discovery with respect to any defendant not named in the AMCC.

## CONCLUSION

For the reasons stated above, defendants respectfully request that the Court enter defendants' Proposed Case Management Order No. 10.

Respectfully Submitted,

ON BEHALF OF AMCC DEFENDANTS

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